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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/806,721	07/11/2001	Bruce Acres	017753-132	7786

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EXAMINER
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LI, QIAN J

ART UNIT	PAPER NUMBER
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1632

13

DATE MAILED: 08/20/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application N .

09/806,721

Applicant(s)

ACRES ET AL.

Examiner

Q. Janice Li

Art Unit

1632

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 03 June 2003.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-17,20,21 and 23-30 is/are pending in the application.
- 4a) Of the above claim(s) 11-17,20,23-25 and 27-29 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-10,21,26 and 30 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 03 June 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All   b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)                      4) ☐ Interview Summary (PTO-413) Paper No(s): \_\_\_\_\_
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)                      5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_                      6) ☐ Other: \_\_\_\_\_

### **DETAILED ACTION**

The amendment and reply filed 6/3/03 has been entered and assigned as paper #11. Claim 18 has been canceled, claim 30 is newly submitted, and claims 1, 6-8, and 21 have been amended. Claims 1-17, 20, 21, 23-30 are pending, however, claims 11-17, 20, 23-25, and 27-29 are withdrawn from further consideration by the Examiner, pursuant to 37 CFR 1.142(b), as being drawn to non-elected inventions, there being no allowable generic or linking claim. Claims 1-10, 21, 26, and 30 are under current examination.

This application contains claims (11-17, 20, 23-25, and 27-29) drawn to an invention nonelected with traverse in Paper No. 8. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

Unless otherwise indicated, previous rejections that have been rendered moot in view of the amendment to pending claims, reply, and Exhibit A will not be reiterated. The amendment has necessitated new grounds of rejection that appear below.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

Art Unit: 1632

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-3, and 30 are newly rejected under 35 U.S.C. 102(e) as being anticipated by *Wittrup et al* (US 6,423,538).

*Wittrup et al* teach a DNA plasmid vector (fig. 3) comprising a gene of interest and a Gal promoter and regulatory sequence such as f1(+) origin, wherein the gene of interest is a single chain anti-TCR antibody KJ16, which recognizes a conformational epitope on the TCR- $\beta$  chain (column 30, lines 34-36). Therefore, *Wittrup et al* anticipate the instant claims.

Claims 1-3, and 30 are newly rejected under 35 U.S.C. 102(a) & (e) as being anticipated by *Burkly et al* (US 5,871,732), and evidenced by *Janeway, Jr. et al* (Immunobiology, 1999).

*Burkly et al* teach a DNA plasmid vector encoding humanized anti-CD4 antibody linked to a promoter and regulatory sequence for expressing the recombinant antibody (column 16, § C, and column 46, § D). CD4 is a T cell receptor comprising TCR- $\alpha$  and TCR- $\beta$  (see enclosed Janeway, Jr. reference), therefore, *Burkly et al* anticipate the instant claims.

Claims 1-6, 21, 26, and 30 are newly rejected under 35 U.S.C. 102(e) as being anticipated by *German et al* (US 6,531,455).

Art Unit: 1632

*German et al* teach a nucleic acid sequence comprising a gene of interest and a promoter and regulatory sequence (column 8, line 48-column 10, line 6), wherein the preferred gene of interest is an anti-CD3 antibody OKTe (column 11, lines 10-11), wherein the nucleic acid is in the form of naked DNA (column 12, line 44), contained in cationic lipid (column 13, lines 7-35), or a viral vector, such as adenoviral vector (column 13, line 48-column 14, line 34). *German et al* also teach using a pharmaceutical carrier when delivering the genetic construct to a mammal (column 20, lines 54-59). Therefore, *German et al* anticipate the instant claims.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-10, 21, 26, and 30 are newly rejected under 35 U.S.C. 103(a) as being unpatentable over *Dixit et al* (US 6,562,797), in view of *Schneck et al* (US 6,448,071) and *Wittrup et al* (US 6,423,538).

*Dixit et al* teach delivering a nucleic acid construct encoding FADD polypeptide to a mammal (abstract), and for the purpose of T cell targeting, including a T-cell specific ligand such as anti-CD3, anti-CD4, and anti-CD28 antibodies in the genetic construct (column 15, lines 52-56), wherein the genetic construct comprising the gene of interest operably linked to a promoter, and could be delivered in a viral vector (column 8, line

Art Unit: 1632

60-column 10, line 45). *Dixit et al* do not teach the details regarding how to construct the T cell targeting sequences.

*Wittrup et al* teach using a plasmid vector expressing an anti-TCR antibody.

*Schneck et al* teach the need in the art for studying the selective interaction of T cell receptors with their cognate ligands, such as peptide/MHC molecules; and for regulating the immune response. For these purposes, they teach using a nucleic acid sequence encoding MHC class II or TCR heterodimers linked with murine antibody heavy and light chains in a baculovirus expression system (abstract), wherein the expression system comprises promoters and enhancers that would ensure the expression of said gene of interest *in vivo* in a target cell (column 13), wherein said nucleic acid sequence could be in the form of a naked polynucleotide or a vector (column 15, line 15), wherein the vector could be complexed with a cationic polymer (column 15, lines, 37-55), wherein the heavy or light chain of the antibody is fused with a transmembrane polypeptide (claims 1 & 9, and column 5, lines 40-41), wherein the transmembrane polypeptide is a glycoprotein TCR  $\alpha/\beta$  chain (claim 12, column 2, line 15), which is on the membrane of CD4<sup>+</sup> T cell (column 2, lines 63-65), thus, the teaching meets limitation of instant claim 7. *Schneck et al* teach a composition comprises said polynucleotide and a copolymer such as polyethylene glycol (column 15, lines 37-55). *Schneck et al* do not teach using an anti-TCR antibodies as the active component of the ligand.

However, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the genetic construct taught by *Schneck et al*, by

Art Unit: 1632

simply substituting the coding sequence for peptide/MHC with that of the anti-TCRs as taught by *Dixit et al* and *Wittrup et al* with a reasonable expectation of success. The ordinary skilled artisan would have been motivated to modify the claimed invention because it is within the knowledge of the skill to make such construct and for *in vivo* T cell targeting or regulation. Thus, the claimed invention as a whole was *prima facie* obvious in the absence of evidence to the contrary.

### ***Conclusion***

No claim is allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Q. Janice Li whose telephone number is 703-308-7942. The examiner can normally be reached on 8:30 am - 5 p.m., Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Deborah J. Reynolds can be reached on 703-305-4051. The fax numbers for the organization where this application or proceeding is assigned are 703-872-9306 for regular communications and 703-872-9307 for After Final communications.

Any inquiry of formal matters can be directed to the patent analyst, Dianiece Jacobs, whose telephone number is (703) 305-3388.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235. The faxing of such papers must conform to the notice published in the Official Gazette 1096 OG 30 (November 15, 1989).

Q. Janice Li  
Examiner  
Art Unit 1632

QJL  
August 8, 2003

ANNE M. WEHBE' PH.D  
PRIMARY EXAMINER

